

REMARKS

Reconsideration and withdrawal of the rejections of this application are requested. The Examiner is thanked for indicating allowable subject matter.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-5, 10-14, 17, 19-21 and 35-51 are under examination in this application. Claims 1, 5, 10-14, 17, 19, 21, 35 and 36 are amended; claim 51 is added to round out the scope of protection to which Applicants are entitled.

Support for the amendments can be found throughout the specification. Specifically, support for the amendment to claim 12 can be found in the paragraph bridging pages 23 and 24 of the specification. Support for claim 51 can be found on page 38, lines 1-2. The remaining amendments have been made to address dependence and formal issues.

No new matter has been added by these amendments.

It is submitted that these claims are and were in full compliance with the requirements of 35 U.S.C. §112. The herein amendments of and additions to the claims are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather, the amendments are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that the herewith amendments should not give rise to any estoppel, as the herewith amendments are not narrowing amendments.

II. THE REJECTIONS UNDER 35 U.S.C. § 112, 1st PARAGRAPH, ARE OVERCOME

Claims 1-6, 12-14, 17-21, 35 and 37-50 were rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking adequate written description and enablement. The rejections are traversed and will be addressed collectively.

The invention involves the retrotransposon of SEQ ID NO:3, described in detail in the application, particularly in Examples 2 and 3, and its use as an expression vector. According to this description, the nucleic acid sequence depicted in Figure 2B comprises two identical long terminal direct repeats (LTRs) of 280 base pairs, that are delineated with an inverted repeat of 6 base pairs, *i.e.* 5' – TGTTGG...CCATCA – 3', as underlined in Figure 2B. It further comprises two long open reading frames (ORFs), *i.e.* the gag ORF of 972 base pairs and the pol ORF of 4728 base pairs, separated from one another only by a UGA termination codon that is annotated as the first STOP in Figure 2B. Also described as characteristic of pCAL is the purine rich sequence AAAACAGG, the pseudoknot immediately downstream of the UGA codon and a four

tandem repeat of the sequence GAAAAA slightly upstream of the UGA codon. An important feature that differentiates pCal from the known retrotransposons is the fact that the gag and pol ORFs of pCall are in the same phase, separated by only a termination codon. See page 49, lines 9-10 of the application.

The Office Action alleges that the broadest embodiments potentially encompass any eukaryotic cell type that might harbor a retrotransposable element. While the application has exemplified *C. albicans*, the claimed retrotransposon and DNA transfer construct can be used to transform other organisms as well, such as *C. maltosa* and *Saccharomyces cerevisiae*. Therefore, limiting the claims to *C. albicans*, would unfairly limit the scope of the invention.

The Office Action further alleges that the claims read on any retrotransposon that comprises a sequence with the recited sequence identity to SEQ ID NO:3. While this is true, it is not an unreasonably broad genus, as all of the species encompassed by it have a specified structural and functional relationship to SEQ ID NO:3, based on sequence homology or ability to hybridize with SEQ ID NO:3. Claim 12 has been amended to increase the amount of sequence identity that is required between the claimed nucleotide sequences and SEQ ID NO:3. As was argued in a previously filed Amendment, stringent hybridization conditions are known in the art, and are taught, for example on page 44, lines 10-17, of the specification. One of ordinary skill in the art could envision the claimed embodiments, and would face no undue experimentation in determining whether a particular retrotransposon has the claimed structure, *i.e.* 95% identical to or hybridizing with SEQ ID NO:3.

It is submitted that the skilled artisan would believe the Applicants to be in possession of the claimed invention at the time of filing, and that s/he would not need to undertake undue experimentation in making and/or using the claimed invention. Therefore, reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph, are requested.

III. THE REJECTIONS UNDER 35 U.S.C. § 112, 2nd PARAGRAPH, ARE OVERCOME

Claims 1-6, 9-14, 17-21, 35-50 were rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite. The rejections are traversed.

Claim 9 has been cancelled and claim 10 has been amended for clarity. As is recited in claim 10, the “internal domain” comprised the gag and pol ORF, flanked by two terminal repeat regions. As discussed above and in the specification, these elements are part of SEQ ID NO:3. In the embodiment of claim 10, a nucleotide sequence encoding a desired protein is also present

in the internal domain. Because this is an additional sequence, the transposable element cannot "consist of" SEQ ID NO:3.

Claim 13 has been amended for clarity, overcoming its rejection.

Claim 19(a) is directed to the sequence of pCal that is located between the terminal repeats; however, as is embodied in claim 10, this sequence can comprise a nucleic acid encoding any desired protein, as the retrotransposon of the invention can be used as an expression vector. Therefore, the sequence between the terminal repeats necessarily comprises a portion of the claimed retrotransposon, but can include additional sequences as well.

Applicants reiterate their arguments that stringent hybridization conditions are known in the art and defined in the specification.

In view of these arguments and amendments, reconsideration and withdrawal of the rejections under 35 U.S.C. §112, second paragraph, are requested.

IV. THE REJECTIONS UNDER 35 U.S.C. §101 ARE OVERCOME

Claims 13, 19-21 and 44-50 were rejected under 35 U.S.C. §101 as allegedly being directed to non-statutory subject matter. The amendments to claim 13 are believed to overcome its rejection on this basis. Claim 19 has been amended to recite an "isolated nucleic acid fragment", obviating the rejection of claims 19-21 and 44-50. Therefore, reconsideration and withdrawal of the rejections under 35 U.S.C. §101 are requested.

CONCLUSION

Applicants believe that the application is in condition for allowance, and favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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